

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION I 5 POST OFFICE SQUARE, SUITE 100 BOSTON, MASSACHUSETTS 02109-3912

URGENT MATTER -- PROMPT REPLY NECESSARY CERTIFIED MAIL: RETURN RECEIPT REQUESTED

February 9, 2016

Mr. Mark Massicotte, Plant Manager Pharmacal Research Laboratories, Inc. 562 Captain Neville Drive Waterbury, CT 06705

RE: NOTICE OF VIOLATION of the Resource Conservation and Recovery Act (RCRA), the Hazardous and Solid Waste Amendments of 1984 (HSWA) and Regulations of Connecticut State Agencies (RCSA): 22a-449(c)-100 through 119.

Dear Mr. Massicotte:

On June 23, 2015, representatives of the United States Environmental Protection Agency ("EPA") conducted a RCRA Compliance Evaluation Inspection. The purpose of this inspection was to determine the compliance of Pharmacal Research Laboratories, Inc., EPA ID No. None, with RCSA 22a-449(c)-100 through 119 and the federal Hazardous Waste Management Regulations found at 40 CFR Parts 260-272. The State of Connecticut has been granted final authorization by EPA to administer certain portions of RCRA.

As a result of the inspection noted above, EPA has determined that your facility violated certain provisions of RCSA 22a-449(c)-100 through 119 and the RCRA regulations, promulgated at 40 CFR Parts 260 through 272. The violations are set forth below:

1. Failure to receive an EPA identification number.

Pharmacal Research Laboratories, Inc. must address the requirements set forth above and must immediately begin and continue to operate in compliance with all applicable Federal and State regulations.

Within (30) thirty calendar days of receipt of this NOTICE, submit a written description, with supporting documentation, of the actions taken to address requirements 1 through 1 above. Submit the information to:

Donald MacLeod, Environmental Engineer U.S. Environmental Protection Agency Office of Environmental Stewardship (OES05-4) 5 Post Office Square, Suite 100 Boston, Massachusetts 02109-3912

Failure to correct the violations as required by this NOTICE may subject the facility to further Federal enforcement action, including the assessment of penalties, pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928. If you have any questions regarding this NOTICE, please contact Donald MacLeod, of my staff, at 617-918-1405.

Sincerely,

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Mary Jane O'Donnell, Manager Office of Environmental Stewardship

cc: Kevin Barret (Western), CTDEP

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